

## **II. REMARKS:**

### **A. Status of the Claims**

The present case is a 371 application of PCT/US2003/028675, filed on September 11, 2003. Claim 1 was originally filed with the 371 application. Claim 1 is rejected in the Official Action mailed on January 24, 2007. Claim 1 is amended and claim 2 is added herein. Support for the amendment to claim 1 can be found, for example, at page 4, lines 17-25; and at page 5, lines 9-18 of the specification. Support for added claim 2 can be found, for example, at page 5, lines 26-31.

### **B. The Claims are Definite**

The Action rejects claim 1 as lacking enablement for the scope of the claim. According to the Action, the specification does not provide enablement for any angiogenic/edematous disorder or all PDE IV inhibitors. Applicants respectfully traverse. Nevertheless, in order to progress the case toward allowance, Applicants have amended the claims to specify the disorder to be treated according to the method of the invention and to list preferred PDE IV inhibitors in claim 1. Applicants reserve the right to pursue additional subject matter disclosed in the specification in properly filed continuation applications. It is believed that the amendments to claim 1 render the enablement rejection moot. Therefore, Applicants respectfully request that the enablement rejection be withdrawn.

### **C. A Terminal Disclaimer Overcomes the Double Patenting Rejection**

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-6 of co-pending application no. 10/660,152. Applicants submit herewith Terminal Disclaimers in compliance with 37 CFR §1.321(c) to overcome the

provisional double patenting rejection. Therefore, Applicants respectfully request that the double patenting rejection based on co-pending application no. 10/660,152 be withdrawn.

**D. The Claims are not Anticipated**

The Action rejects claim 1 as being anticipated by Schudt. Schudt is said to teach the composition containing PDE-IV inhibitors for the treatment of angiogenesis disorders such as retinopathy. Applicants respectfully traverse.

The present invention is directed to methods for treating macular edema by administering a selective PDE-IV inhibitor selected from a defined group of compounds. Schudt appears to discuss the use of a combination of a PDE inhibitor and either an adenylate cyclase agonist or a guanylate cyclase agonist to treat disease states which are based on acute or chronic obstruction of vessels and/or bronchi, acute or chronic inflammation and/or edema formation. Schudt contains a long list of patent applications and patents directed to PDE inhibitors generally. Schudt suggests that PDE5, PDE4, PDE3, or PDE 3/4 inhibitors may be used in the described combinations and methods.

Schudt does not teach the use of the specific compounds of the current invention for the treatment of macular edema. In fact, Schudt does not discuss the use of PDE-IV inhibitors by themselves at all. Rather, Schudt appears to suggest that such compounds would not be as effective if administered alone. Specifically, Schudt states that “as a result of the combination according to the invention of PDE inhibitor and AC agonist or GC agonist, the individual components can be used in concentrations which are not very active or not active at all on their own. By this means, side effects of the individual components which would occur at the intrinsically active concentrations of PDE inhibitor or AC agonist or GC

agonist on single administration are avoided by the low concentration in the combination.” (see column 3, lines 26-34; emphasis added). Thus, it is submitted that Schudt doesn’t even teach the use of a pharmaceutically effective amount for a composition containing only a PDE-IV inhibitor, such as that used in the methods of the invention.

It is well stated that for a prior art reference to anticipate a claimed invention, that reference must set forth every element in the claim, either expressly or inherently. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F. 2d 628, 631 (Fed. Cir. 1987) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). In other words, to support a rejection under Section 102, a reference must show all features of the rejected claim(s). *Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1569 (Fed. Cir. 1992). The Federal Circuit has stated that “absence of a claim element from a prior art reference negates anticipation.” *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 224 USPQ 409 (Fed. Cir. 1984).

Since Schudt lacks a teaching of the use of the particular PDE-IV inhibitors described, alone, for the treatment of macular edema, it is believed that Schudt cannot anticipate the claimed invention.

In light of the foregoing arguments, it is respectfully requested that the anticipation rejection based on Schudt be withdrawn.

#### **E. Conclusion**

Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

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The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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